
STATUTORY INSTRUMENTS

1993 No. 2360

The Clinical Thermometers (EEC Requirements) Regulations 1993

**PART I
GENERAL**

Citation and commencement

1. These Regulations may be cited as the Clinical Thermometers (EEC Requirements) Regulations 1993 and shall come into force on 21st October 1993.

Interpretation

2.—(1) In these Regulations except where the context otherwise requires—

“approved body” means a body approved by the Secretary of State under regulation 6;

“clinical thermometer” means a thermometer to which these Regulations apply in accordance with regulation 3;

“the Directive” means Council Directive No. [76/764/EEC](#) on the approximation of the laws of the member States on clinical mercury-in-glass, maximum reading thermometers(1), as amended by Council Directive No. [83/128/EEC](#)(2) and Commission Directive No. [84/414/EEC](#)(3);

“inspector” means a person authorised in writing by the Secretary of State to be an inspector for the purposes of these Regulations;

“the 1988 Regulations” means the Measuring Instruments (EEC Requirements) Regulations 1988(4);

(2) In these Regulations, unless the context otherwise requires, any reference to a numbered regulation is a reference to the regulation bearing that number and any reference in a regulation to a numbered paragraph is a reference to the paragraph of that regulation bearing that number.

Application of Regulations

3. These Regulations apply to clinical mercury-in-glass, maximum reading thermometers designed to measure the internal temperature of humans or animals.

(1) O.J. No. L262, 27.9.1976, p.139.

(2) O.J. No. L91, 9.4.1983, p.29.

(3) O.J. No. L228, 25.8.1984, p.25.

(4) S.I. [1988/186](#), amended by S.I. [1988/1128](#) and [1992/1579](#).

Pattern approval and initial verification: the EEC signs and marks

4.—(1) The EEC signs and marks referred to in these Regulations are the following signs and marks—

- (a) the sign of EEC pattern approval described in paragraph 1 of Schedule 1 to the 1988 Regulations or the alternative sign in paragraph 1 of the Schedule to these Regulations;
- (b) the sign of EEC limited pattern approval described in paragraph 2 of Schedule 1 to the 1988 Regulations or the alternative sign in paragraph 2 of the Schedule to these Regulations;
- (c) the mark of EEC initial verification described in paragraph 5 of Schedule 1 to the 1988 Regulations or the alternative mark in paragraph 3 of the Schedule to these Regulations.

(2) In these Regulations, references to the United Kingdom version of a sign or mark referred to in paragraph (1) are references to the sign or mark appropriate, in accordance with the provisions of Schedule 1 to the 1988 Regulations or the Schedule to these Regulations (as the case may be), for an EEC pattern approval granted, or (as the case may be) an EEC initial verification carried out, in the United Kingdom.

Free movement of clinical thermometers which bear sign of EEC pattern approval and mark of EEC initial verification

5. Subject to regulation 12 (temporary prohibition of sale or use) any rule of law, statutory or otherwise, which prohibits or restricts the sale or entry into use of clinical thermometers shall not apply to any thermometer which bears the sign of EEC pattern approval and the mark of EEC initial verification.

Approval of bodies

6.—(1) On application made by the body, the Secretary of State may approve one or more bodies of persons—

- (a) to consider applications for EEC pattern approval, to conduct any examination for EEC pattern approval and to grant if appropriate, a certificate of EEC pattern approval in respect of clinical thermometers; and
- (b) to carry out EEC initial verification and to affix the EEC mark of initial verification in respect of clinical thermometers.

(2) Any such approval—

- (a) may be given for an unlimited period, or for a specified period, or for specified purposes; and
- (b) may be given subject to conditions (including conditions which are to apply upon or following withdrawal of the approval).

(3) The Secretary of State shall withdraw an approval if the body so requests and may withdraw an approval if the body ceases to comply with any such conditions.

(4) In a case where the Secretary of State—

- (a) refuses an application for approval under paragraph (1) above or imposes any condition more onerous than any of those proposed by the body or imposes any condition at all when the body proposed none; or
- (b) withdraws an approval under paragraph (3) above,

he shall inform the body of the grounds for the refusal, imposition of that condition or withdrawal of approval, as the case may be.

(5) If for any reason an approved body ceases to be an approved body under this regulation, the Secretary of State may designate another approved body to take over its functions in respect of such cases as he may specify.

(6) The approved body may charge a fee in accordance with paragraphs (7), (8) and (9) for anything done in, or in connection with, performing a function under these Regulations.

(7) Except as provided by paragraph (8) the fee charged in respect of anything done shall not exceed an amount which reasonably represents the cost incurred, or to be incurred in doing it.

(8) Where the approved body is a body the activities of which are carried on for profit, the fee for doing anything may include an amount representing a profit which is reasonable in the circumstances, having regard to—

- (a) the character and extent of the work done or to be done by the approved body; and
- (b) the commercial rate normally charged in respect of profit for that work or similar work.

(9) The approved body may require payment of a fee or a reasonable estimate of the fee, in advance of carrying out the work in respect of which the fee is payable and as a condition of doing that work.